

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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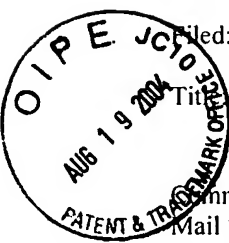
Applicant(s): HSU et al. Group Art Unit: 1614

Serial No.: 10/732,782 Examiner: : Unknown

Filed: December 10, 2003 Docket No.: 275.0007 0101

Confirmation No.: 6883

Title: CHEMOPREVENTIVE AND THERAPEUTIC ASPECTS OF POLYPHENOLIC COMPOSITIONS AND ASSAYS



Commissioner for Patents  
Mail Stop Amendment  
P.O. Box 1450  
Alexandria, VA 22313-1450

We are transmitting the following documents along with this Transmittal Sheet (which is submitted in triplicate):

- ☒ **Small entity status is entitled to be asserted in the above-identified application.**
- ☒ An itemized return postcard.
- ☐ A Petition for Extension of Time for month.
- ☒ An Information Disclosure Statement (2 pgs); 1449 forms (12 pgs); and copies of 132 documents cited on the 1449 forms.
- ☐ A check in the amount of \$\_\_, representing \_\_.
- ☐ A certified copy of a \_\_ application, Serial No. \_\_, filed \_\_\_\_, the right of priority of which is claimed under 35 U.S.C. §119.
- ☐ Other:
- ☐ Amendment ☐ No Additional fee is required. ☐ The fee has been calculated as shown:

Fee Calculation for Claims Pending After Amendment					
	Pending Claims after Amendment (1)	Claims Paid for Earlier (2)	Number of Additional Claims (1-2)	Cost per Additional Claim	Additional Fees Required
Total Claims				x \$9 =	
Independent Claims				x \$43 =	
One or More New Multiple Dependent Claims Presented? If Yes, Add \$145 Here →					
Total Additional Claim Fees Required					

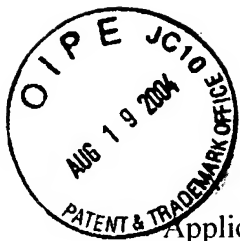
Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 13-4895. Triplicate copies of this sheet are enclosed.

**CERTIFICATE UNDER 37 C.F.R. §1.8:** The undersigned hereby certifies that this Transmittal Letter and the paper(s), as described hereinabove, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Commissioner for Patents, Mail Stop Amendment, P.O. Box 1450, Alexandria, VA 22313-1450, on this 12 day of August, 2004.

MUETING, RAASCH & GEBHARDT, P.A.  
Customer Number: 26813

By: *Nancy A. Johnson*  
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(SMALL ENTITY TRANSMITTAL UNDER RULE 1.8)



PATENT  
Docket No.275.0007 0101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	HSU et al.	)	Group Art Unit:	1614
		)		
Serial No.:	10/732,782	)	Examiner:	Unknown
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		)		
Filed:	December 10, 2003	)		
		)		
For:	CHEMOPREVENTIVE AND THERAPEUTIC ASPECTS OF POLYPHENOLIC COMPOSITIONS AND ASSAYS			

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with C.F.R. §§ 1.97 *et. seq.*, the materials enclosed herewith are brought to the attention of the Examiner as possibly being of interest in connection with the above-identified patent application. Per M.P.E.P. § 609, the information cited in the present Information Disclosure Statement shall not be construed to be an admission that the information is, or is considered to be, material to patentability. Consideration of each of the documents listed on the attached 1449 form(s) is respectfully requested. As this patent application was filed after June 30, 2003 copies of the U.S. patents and U.S. patent application publications listed on the attached 1449 form(s) have not been submitted. Pursuant to the provisions of M.P.E.P. §609, Applicants further request that a copy of the 1449 form(s), marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

It is believed that no fee is due, as this Information Disclosure Statement is filed prior to the receipt of any Action on the merits. However, in the event a fee is due, please charge any fee or credit any overpayment to Account No. 13-4895.

*Information Disclosure Statement*

*Serial No. 10/732,782*

*Filed: December 10, 2003*

CHEMOPREVENTIVE AND THERAPEUTIC ASPECTS OF POLYPHENOLIC COMPOSITIONS AND ASSAYS

This application claims the benefit of U.S. Provisional Application Serial No. 60/432,086, filed December 10, 2002.

The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number, if they can be of any assistance during prosecution of the present application.

CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 12 day of August, 2004.

Respectfully submitted for  
HSU et al.

By  
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August 12, 2004  
Date

NAJ/sjt

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**INFORMATION  
DISCLOSURE  
STATEMENT**

Atty. Docket No.: 275.00070101

Serial No.: 10/732,782

Applicant(s): Hsu et al.

Confirmation No.: 6883

Application Filing Date: 12/10/03

Group: 1614

Information Disclosure Statement mailed: \_\_\_\_\_


**U.S. PATENT DOCUMENTS**

Examiner Initial	Copy Enclosed	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
		2003/0134300	07/17/03	Golub et al.			

**FOREIGN PATENT DOCUMENTS**

Examiner Initial	Copy Enclosed	Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No

**OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)**

Examiner Initial	Copy Enclosed	Document Description
	✓	Ahmad et al., "Identification and Characterization of Murine Caspase-14, a New Member of the Caspase Family," <i>Cancer Res</i> , 1998;58: 5201-5205
	✓	Ahmad et al., "Green Tea Constituent Epigallocatechin-3-Gallate and Induction of Apoptosis and Cell Cycle Arrest in Human Carcinoma Cells," <i>J Natl Cancer Inst</i> , 1997;89: 1881-1886
	✓	Appel et al., "Metabolic stability of experimental chemotherapeutic agents in hepatocyte: tumor cell co-cultures," <i>Cancer Chemother Pharmacol</i> , 1986;17: 47-52
	✓	Arteaga et al., "Transforming Growth Factor $\beta$ : Potential Autocrine Growth Inhibitor of Estrogen Receptor-negative Human Breast Cancer Cells," <i>Cancer Res</i> , 1988;48: 3898-3904
	✓	Azuma et al., "Immortalization of Normal Human Salivary Gland Cells with Duct-, Myoepithelial-, Acinar-, or Squamous Phenotype by Transfection with SV40 Ori-Mutant Deoxyribonucleic Acid," <i>Lab Invest</i> , 1993;69: 24-42
	✓	Bacus et al., "Neu differentiation factor (Heregulin) activates a p53-dependent pathway in cancer cells," <i>Oncogene</i> , 1996 12:2535-2547
	✓	Balasubramanian et al., "Green Tea Polyphenol Stimulates a Ras, MEKK1, MEK2, and p38 Cascade to Increase Activator Protein 1 Factor-dependent Involucrin Gene Expression in Normal Human Keratinocytes," <i>J Biol Chem</i> , 18 January 2002;277(3): 1828-1836

<b>EXAMINER</b>	<b>Date Considered</b>
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Examiner Initial	Copy Enclosed	Document Description
	✓	Barthelman et al., "(-)-Epigallocatechin-3-gallate inhibition of ultraviolet B-induced AP-1 activity," <i>Carcinogenesis</i> , 1998;(19)12:2201-2204
	✓	Bikle et al., "Calcium- and vitamin D-regulated keratinocyte differentiation," <i>Mol Cell Endocrinol</i> , 2001;177: 161-171
	✓	Blagosklonny et al., "Taxol Induction of p21 <sup>WAF1</sup> and p53 Requires c-raf-1," <i>Cancer Res</i> , 1995;55: 4623-4626
	✓	Blanc et al., "Caspase-3 Is Essential for Procaspase-9 Processing and Cisplatin-induced Apoptosis of MCF-7 Breast Cancer Cells", <i>Cancer Res</i> , 2000;60: 4386-4390
	✓	Bors et al., "Electron Paramagnetic Resonance Studies of Radical Species of Proanthocyanidins and Gallate Esters," <i>Arch Biochem Biophys</i> , 2000;374: 347-355
	✓	Bravo, "Polyphenols: Chemistry, Dietary Sources, Metabolism, and Nutritional Significance," <i>Nutri Rev</i> , 1998;56(11): 317-333
	✓	Cecconi, "Apaf1 and the apoptotic machinery," <i>Cell Death Diff.</i> , 1999; 6: 1087-1098
	✓	Chai et al., "Contribution of hydrogen peroxide to the cytotoxicity of green tea and red wines," <i>Biochem Biophys Res Commun</i> , 2003;304:650-654
	✓	Chang et al., "DOK, A Cell Line Established from Human Dysplastic Oral Mucosa, Shows a Partially Transformed Non-malignant Phenotype," <i>Int J Cancer</i> , 1992;52:896-902
	✓	Chaturvedi et al., "Apoptosis in Proliferating, Senescent, and Immortalized Keratinocytes," <i>J Biol Chem</i> , 13 August 1999;274(33): 23358-23367
	✓	Chen et al., "Activation of Antioxidant-Response Element (ARE), Mitogen-Activated Protein Kinases (MAPKs) and Caspases by Major Green Tea Polyphenol Components during Cell Survival and Death," <i>Arch Pharm Res</i> , 2000;23: 605-612
	✓	Chen et al., "Green tea epigallocatechin gallate shows a pronounced growth inhibitory effect on cancerous cells but not on their normal counterparts," <i>Cancer Lett.</i> , 1998;129:173-179

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	✓	Chen et al., "Tea Catechins Protect against Lead-Induced Cytotoxicity, Lipid Peroxidation, and Membrane Fluidity in HepG2 Cells," <i>Toxicol Sci</i> , 2002;69: 149-156
	✓	Chung et al., "Inhibition of Activator Protein 1 Activity and Cell Growth by Purified Green Tea and Black Tea Polyphenols in H-ras-transformed Cells: Structure-Activity Relationship and Mechanism Involved," <i>Cancer Res</i> , 1999;59: 4610-4617
	✓	Cuvillier et al., "Sphingosine generation, cytochrome c release, and activation of caspase-7 in doxorubicin-induced apoptosis of MCF7 breast adenocarcinoma cells," <i>Cell Death Differ</i> , 2001;8: 162-71
	✓	Dashwood et al., "Inhibition of $\beta$ -catenin/Tcf activity by white tea, green tea, and epigallocatechin-3-gallate (EGCG): minor contribution of H <sub>2</sub> O <sub>2</sub> at physiologically relevant EGCG concentrations," <i>Biochem Biophys Res Commun</i> , 2002;296: 584-588
	✓	Deschenes et al., "Role of p27 <sup>Kip1</sup> in Human Intestinal Cell Differentiation," <i>Gastroenterology</i> , 2001;120: 423-438
	✓	Di Cunto et al., "Inhibitory Function of p21 <sup>Cip1/WAF1</sup> in Differentiation of Primary Mouse Keratinocytes Independent of Cell Cycle Control," <i>Science</i> , 1998;280: 1069-1072
	✓	Dong, "Effects of food factors on signal transduction pathways," <i>Biofactors</i> , 2000;12: 17-28
	✓	Dransfield et al., "8-C1-Adenosine Induces Growth Arrest without Differentiation of Primary Mouse Epidermal Keratinocytes," <i>J Invest Dermatol</i> , 2001;117(6):1588-1593
	✓	Dvorakova et al., "Pharmacokinetics of the green tea derivative, EGCG, by the topical route of administration in mouse and human skin," <i>Cancer Chemother Pharmacol</i> , 1999;43: 331-335
	✓	Eckhart et al., "Caspase-14: Analysis of Gene Structure and mRNA Expression during Keratinocyte Differentiation," <i>Biochem Biophys Res Commun</i> , 2000;277:655-659

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	✓	Eckhart et al., "Terminal Differentiation of Human Keratinocytes and Stratum Corneum Formation is Associated with Caspase-14 Activation," <i>J Invest Dermatol</i> , 2000;115:1148-1151
	✓	El-Mir et al., " <i>In vitro</i> test to determine the effect of cytostatic drugs on co-cultured rat hepatocytes and hepatoma cells," <i>Int J Exp Pathol</i> , 1998;79:109-115
	✓	Fu, "The Effects on Cell Growth of Tea Polyphenols Acting as a Strong Anti-peroxidant and an Inhibitor of Apoptosis in Primary Cultured Rat Skin Cells," <i>Biomed Environ Sci</i> , 2000;13: 170-179
	✓	Fujita et al., "Interferon- $\beta$ Gene Regulation: Tandemly Repeated Sequences of a Synthetic 6 bp Oligomer Function as a Virus-Inducible Enhancer," <i>Cell</i> , 1987;49: 357-367
	✓	Halliwell, "Oxidative stress in cell culture: an under-appreciated problem?," <i>FEBS Lett</i> , 2003;540: 3-6
	✓	Harada et al., "Absence of the Type I IFN System in EC Cells: Transcriptional Activator (IRF-1) and Repressor (IRF-2) Genes are Developmentally Regulated," <i>Cell</i> , 1990;63: 303-312
	✓	Higdon, et al., "Tea Catechins and Polyphenols: Health Effects, Metabolism, and Antioxidant Functions," <i>Crit Rev Food Sci Nutr</i> , 2003;43(1): 89-143
	✓	Hong et al., "Stability, Cellular Uptake, Biotransformation, and Efflux of Tea Polyphenol (-)-Epigallocatechin-3-Gallate in HT-29 Human colon Adenocarcinoma Cells," <i>Cancer Res.</i> , 2002;62: 7241-7246
	✓	Hsu et al., "Green Tea Polyphenol Targets the Mitochondria in Tumor Cells Inducing Caspase 3-Dependent Apoptosis," <i>Anticancer Res</i> , 2003; 23:1533-1540
	✓	Hsu et al., "Green Tea Polyphenols Induce Differentiation and Proliferation in Epidermal Keratinocytes," <i>J Pharmacol Exp Ther</i> , 2003;306: 29-34
	✓	Hsu et al., "Chemoprevention of oral cancer by green tea." <i>General Dentistry</i> , 2002 Mar-Apr;50(2): 140-146

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	✓	Hsu et al., "Chemopreventive effects of green tea polyphenols correlate with reversible induction of p57 expression," <i>Anticancer Research</i> , 2001 Nov-Dec;21(6A): 3743-3478.
	✓	Hsu et al., "Induction of p57 is required for cell survival when exposed to green tea polyphenols," <i>Anticancer Research</i> , 2002 Nov-Dec;22(6C): 4115-4120
	✓	Hsu et al., "Chemopreventive effects of green tea polyphenol is associated with caspase 14 induction in epidermal keratinocytes," AACR Annual Meeting, Orlando, Fl., March 29, 2004. Abstract
	✓	Hu et al., "Caspase-14 Is a Novel Developmentally Regulated Protease," <i>J Biol Chem</i> , 6 November 1998;273(45): 29648-29653
	✓	Huang et al., "Inhibitory effect of topical application of a green tea polyphenol fraction on tumor initiation and promotion in mouse skin," <i>Carcinogenesis</i> , 1992;13(6): 947-954
	✓	Huynh et al., <i>Journal of Dental Research</i> , 201;80: 176
	✓	Irwin et al., "Role for the p53 homologue p73 in E2F-1-induced apoptosis," <i>Nature</i> , 2000;407: 645-648
	✓	Ishii et al., "Prevention of Mammary Tumorigenesis in Acatalasemic Mice by Vitamin E Supplementation," <i>Jpn J Cancer Res</i> , 1996;87: 680-684
	✓	Islam et al., "Involvement of Caspase-3 in Epigallocatechin-3-gallate-Mediated Apoptosis of Human Chondrosarcoma Cells," <i>Biochem Biophys Res Commun</i> , 2000;270: 793-797
	✓	Ito et al., "Expression of p57/Kip2 protein in extrahepatic bile duct carcinoma and intrahepatic cholangiocellular carcinoma," <i>Liver</i> , 2000;22: 145-149
	✓	Ito et al., "Expression of p57/Kip2 Protein in Hepatocellular Carcinoma," <i>Oncology</i> , 2001;61: 221-225
	✓	Ito et al., "Expression of p57/Kip2 Protein in Pancreatic Adenocarcinoma," <i>Pancreas</i> , 2001;23(3): 246-50
	✓	Ito et al., "Expression of p57/Kip2 protein in normal and neoplastic thyroid tissues," <i>Int J Mol Med</i> , 2002;9: 373-376

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	✓	Janicke et al., "Caspase-3 Is Required for DNA Fragmentation and Morphological Changes Associated with Apoptosis," <i>J Biol Chem</i> , 17 April 1998;273(16): 9357-9360
	✓	Jin et al., "Different Effects of Five Catechins on 6-Hydroxydopamine-Induced Apoptosis in PC12 Cells," <i>J Agric Food Chem</i> , 2001;49: 6033-6038
	✓	Jung et al., "A Potential Role for Ceramide in the regulation of Mouse Epidermal Keratinocyte Proliferation and Differentiation," <i>J Invest Dermatol</i> , 1998;110: 318-323
	✓	Kagawa et al., "Deficiency of Caspase-3 in MCF7 Cells Blocks Bax-mediated Nuclear Fragmentation but not Cell Death," <i>Clin Cancer Res</i> , 2001;7:1474-1480
	✓	Katiyar et al., "Inhibition of UVB-induced oxidative stress-mediated phosphorylation of mitogen-activated protein kinase signaling pathways in cultured human epidermal keratinocytes by green tea polyphenol(-)-epigallocatechin-3-gallate," <i>Toxicol Appl. Pharmacol</i> , 2001;176: 110-117
	✓	Katiyar et al., "Green tea polyphenol (-)-epigallocatechin-3-gallate treatment of human skin inhibits ultraviolet radiation-induced oxidative stress," <i>Carcinogenesis</i> , 2001;22(2): 287-294
	✓	Katiyar, et al., "Green Tea Polyphenolic antioxidants and skin photoprotection (Review)," <i>Int J Oncol</i> , 2001;18:1307-1313
	✓	Kennedy et al., "Growth inhibitory effect of green tea extract in Ehrlich ascites tumor cells involves cytochrome c release and caspase activation," <i>Cancer Lett</i> , 2001;166: 9-15
	✓	King, et al., "Characteristics and occurrence of phenolic phytochemicals," <i>J Am Diet Assoc</i> , 1999;99:213-218
	✓	Kiningham, et al., "Overexpression of Manganese Superoxide Dismutase Selectively Modulates the Activity of Jun-associated Transcription Factors in Fibrosarcoma Cells," <i>Cancer Res</i> , 1997;57: 5265-5271
	✓	Kong et al., "Differential Activation of MAPK and ICE/Ced-3 Protease in Chemical-Induced Apoptosis," <i>Restor Neurol Neurosci</i> , 1998;12: 63-70

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	✓	Lambert, et al., "Cancer chemopreventive activity and bioavailability of tea and tea polyphenols," <i>Mutat Res</i> , 2003 Feb- Mar;523-524: 201-208
	✓	Lapp et al., "Macroarray analysis of tea polyphenol-treated normal versus malignant epithelial cells" Medical College of Georgia School of Denistry, USA. AADR Annual Meeting, Honolulu, HI. March 12, 2004.
	✓	Lee et al., "Cloning of p57 <sup>KIP2</sup> , a cyclin-dependent kinase inhibitor with unique domain structure and tissues distribution," <i>Genes Dev</i> , 1995;9: 639-649
	✓	Lee et al., "Differentiation of Cultured Human Epidermal Keratinocytes at High Cell Densities is Mediated by Endogenous Activation of The Protein Kinase C Signaling Pathway," <i>J Invest Dermatol</i> , 1998;111(5): 762-766
	✓	Lee et al., "Inhibition of 1,2,4-benzenetriol-generated active oxygen species and induction of phase II enzymes by green tea polyphenols," <i>Chem Biol Interact</i> , 1995;98: 283-301
	✓	Lee et al., "Protective Effect of Green Tea Polyphenol (-)-Epigallocatechin Gallate and Other Antioxidants on Lipid Peroxidation in Gerbil Brain Homogenates," <i>Phytother Res</i> , 2003;17:206-209
	✓	Leist, et al., "Four Deaths and a Funeral: From Caspases to Alternative Mechanisms," <i>Nat Rev Mol Cell Bio</i> , 2001;2:589-98
	✓	Liberto, et al., "Growth factor-dependent induction of p21 <sup>CIP1</sup> by the green tea polyphenol, epigallocatechin gallate," <i>Cancer Lett</i> , 2000;154: 151-161
	✓	Lin et al., "Cancer Chemoprevention by Tea Polyphenols through Mitotic Signal Transduction Blockade," <i>Biochem Pharmacol</i> , 1999;58: 911-915
	✓	Lippens et al., "Epidermal differentiation does not involve the pro-apoptotic executioner caspases, but is associated with caspase-14 induction and processing," <i>Cell Death Differ.</i> , 2000;7:1218-1224
	✓	Lissy et al., "A common E2F-1 and p73 pathway mediates cell death induced by TCR activation," <i>Nature</i> , 2000; 407: 642-5
	✓	Long et al., "Generation of Hydrogen Peroxide by "Antioxidant" Beverages and the Effect of Milk Addition. Is Cocoa the Best Beverage?," <i>Free Rad Res</i> , 1999;31: 67-71

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	✓	Makino et al., "Evaluation of Quantitative Detection of mRNA by the reverse transcription-polymerase chain reaction," <i>Technique</i> , 1990;2: 295-301
	✓	Martinez et al., "Coordinated changes in cell cycle machinery occur during keratinocyte terminal differentiation," <i>Oncogene</i> , 1999;18: 397-406
	✓	Milton, "Nutritional Characteristics of Wild Primate Foods: Do the Diets of our Closest Living Relatives Have Lessons for Us?," <i>Nutrition</i> , 1999;15(6): 488-498
	✓	Missero et al., "Involvement of the cell-cycle inhibitor <i>Cip1/WAF1</i> and the E1A-associated p300 protein in terminal differentiation," <i>Proc Natl Acad Sci USA</i> , June 1995;92: 5451-5455
	✓	Miyazawa, "Absorption, metabolism and antioxidative effects of tea catechin in humans," <i>Biofactors</i> , 2000;13: 55-59
	✓	Moroni et al., "Apaf-1 is a transcriptional target for E2F and p53," <i>Nat Cell Biol</i> , 2001;3:552-8
	✓	Nakagawa et al., "Fenton Reaction is Primarily Involved in a Mechanism of (-)-Epigallocatechin-3-gallate to Induce Osteoclastic Cell Death," <i>Biochem Biophys Res Comm</i> , 2002;292: 94-101
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	✓	Zou et al., "Apaf-1, a human protein homologous to C.elegans CED-4, participates in cytochrome c-dependent activation of caspase-3," <i>Cell</i> , 1997;90: 405-413.

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